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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/499,875	02/08/2000	Richard Griffey	IBIS-0261	1850

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Woodcock Washburn Kurtz
Mackiewicz & Norris LLP
One Liberty Place
46th Floor
Philadelphia, PA 19103

EXAMINER
FRIEND, TOMAS H F

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
file copy	09/499,875	GRIFFEY ET AL.	
	Examiner	Art Unit	
	Tomas Friend	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-32 and 34-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-32 and 34-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Detailed Action

Change of Art Unit Designation

Please note: The Art Unit location of this application in the PTO has changed from Art Unit 1627 to Art Unit 1639. To aid in matching papers to this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 July 2002 (Paper No. 14) has been entered.

Receipt is acknowledged of an amendment and response to an office action on 08 November 2002 (Paper No. 16).

Status of the Claims

Claims 30-32 and 34-46 are pending in the present application. Claim 33 was cancelled in Paper No. 16 and claims 1-29 and 47-120 were cancelled in Paper No. 14.

Withdrawn Rejections

All outstanding rejections are withdrawn.

Claims Rejections – Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 30-32 and 34-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-19 of U.S. Patent No. 6,329,146 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed method is obvious over the method disclosed in the '146 patent.

The present claims are drawn to a method of selecting members of a library of 2-100,000 compounds (of less than 200 Daltons and having fewer than 4 rotatable bonds) that can form a non-covalent complex with a target RNA molecule comprising: [1] mixing a standard ligand with an excess of target RNA molecule; [2] introducing the mixture into an electrospray mass spectrometer and adjusting the operational parameters of the spectrometer so that the relative ion abundance signal of the standard ligand- target RNA molecule complex is between 1% and 30% that of the unbound target molecule; [3] introducing 2-8 compounds from the library into a test mixture of standard ligand-target RNA molecule; [4] identifying members of the groups of compounds that form non-covalent complexes with the target RNA molecule by discerning

relative ion abundance signals that arise from complexes formed between the target RNA molecule and members of the croups of compounds and identifying the compounds by their relative molecular masses; and [5] storing and cross-indexing relative abundance and stoichiometry data of complexes in a relational database.

The '146 patent teaches a method for identifying in a combinatorial mixture compounds which bind to a target RNA comprising: [1] providing a complex of RNA target and standard binding compound; [2] combining the complex with a combinatorial mixture of compounds; [3] collecting mass spectral (relative) ion abundance data on the mixture formed in [2] and using (relative) ion abundance data collected for the complex in [1] to afford information that allows the determination of which compounds from the combinatorial mixture bind to the target RNA.

The '146 method clearly requires the selection of a mass spectrometer and collecting ion abundance data for a standard ligand-RNA complex as well as a mixture including the standard ligand-RNA complex plus compounds form a combinatorial mixture. Column 48 of the '146 patent teaches that the target molecule must be in excess over the standard ligand and columns 48-49 teach the use of relational databases for the results of electrospray mass spectroscopy embodiments of the cited method. The referenced method can be used with combinatorial libraries of potential ligands from metal ions to small organic molecules (i.e. less than 200 Daltons and fewer than 4 rotatable bonds) to large molecules including, for example, 20-5000 compounds. The method is exemplified using a library of 216 organic molecules and paromomycin as a standard ligand.

The '146 patent does not specify particular relative signal strengths libraries limited to compounds of various molecular weight ranges or numbers of rotatable bonds. Such optimizations and selections of parameters were well within the abilities of one of ordinary skill in the art at the time that the invention was made.

Claims Rejections – 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 30-32 and 34-46 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,329,146 B1 Crooke et al. December 2001.

The present claims are drawn to a method of selecting members of a library of 2-100,000 compounds that can form a non-covalent complex with a target RNA molecule comprising: [1] mixing a standard ligand with an excess of target RNA molecule; [2] introducing the mixture into an electrospray mass spectrometer and adjusting the operational parameters of the spectrometer so that the relative ion abundance signal of the standard ligand- target RNA molecule complex is between 1% and 30% that of the unbound target molecule; [3] introducing 2-8 compounds from the library into a test mixture of standard ligand-target RNA molecule; [4] identifying members of the groups of compounds that form non-covalent complexes with the target RNA molecule by discerning relative ion abundance signals that arise from complexes formed between the target RNA molecule and members of the croups of compounds and identifying the compounds by their relative molecular masses; and [5] storing and cross-indexing relative abundance and stoichiometry data of complexes in a relational database.

The '146 patent discloses a method for identifying in a combinatorial mixture compounds which bind to a target RNA comprising: [1] providing a complex of RNA target and standard binding compound; [2] combining the complex with a combinatorial mixture of compounds; [3] collecting mass spectral (relative) ion abundance data on the mixture formed in [2] and using (relative) ion abundance data collected for the complex in [1] to afford information that allows the determination of which compounds from the combinatorial mixture bind to the target RNA.

The '146 method clearly requires the selection of a mass spectrometer and collecting ion abundance data for a standard ligand-RNA complex as well as a mixture including the standard

ligand-RNA complex plus compounds form a combinatorial mixture. Column 48 of the '146 patent discloses that the target molecule must be in excess over the standard ligand and columns 48-49 disclose the use of relational databases for the results of electrospray mass spectroscopy embodiments of the cited method. The referenced method can be used with combinatorial libraries of potential ligands from metal ions to small organic molecules (i.e. less than 200 Daltons and fewer than 4 rotatable bonds) to large molecules including, for example, 20-5000 compounds. The method is exemplified using a library of 216 organic molecules and paromomycin as a standard ligand.

Conclusion

3. No claims are allowed.

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tomas Friend** at telephone number **(703) 308-4548**. The examiner works on a flexible schedule of four ten-hour days per week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Tomas Friend, Ph.D.
07 February 2003

ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600